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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,952	09/29/2000	Poul Bach	5974.200-US	1106

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NEW YORK, NY 10110

EXAMINER

LEITH, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/15/2004

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/675,952

Applicant(s)

BACH, POUL

Examiner

Patricia Leith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 26, 34, 35 and 39-56 is/are pending in the application.
4a) Of the above claim(s) 11, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 26, 39-50 and 53-56 is/are rejected.
- 7) ☒ Claim(s) 10, 51 and 52 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/10/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-11, 26, 34, 35 and 39-56 are pending in the application. Claims 39-52 were inadvertently omitted from the previous Office Action.

Claims 11 and 34-35 were withdrawn from examination on the merits as being directed toward a non-elected invention in Paper No. 13.

Claims 1-10, 26 and 39-56 were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 103

Claims 1-6 and 9 remain rejected under 35 U.S.C. 103(a) and claims 39-49 and 53-56 are newly rejected as being unpatentable over Kamel et al. (US 5,230,822).

Claims 39-49 are drawn to the size of the enzyme core unit in terms of its diameter in its longest dimension is no more than 700 or 600 μm or between 1—and 500 μm , wherein the size of the core unit in terms of it's relative mass compared to the overall mass of the granule is up to about 20% or up to about 15% or up to about 10%

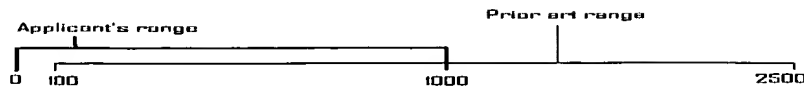
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or up to about 5%, wherein the enzyme content in the core unit is at least 30%, or at least 50% or at least 70% or at least 90% by weight of the enzyme core unit and wherein the ration of D90-D10/D50 comprises several different values (claims 50-52).

Applicant's arguments with regard to claims 1-6 and 9-10 were fully considered but were not found convincing.

Applicant's principal argument resides in the contention that the new limitation which reads "and wherein the size of the enzyme core unit, in terms of it's diameter in it's longest dimension is no more than 1000 μ m" distinguishes the claims from the prior art: "Indeed, no where do Kamel et al. teach or suggest that the size of the core unit (or the shell unit), and relative size of the core unit compared to the granule is a result effective variable with respect to advantages obtained by the present invention, including, in particular, in preparation and handling of the enzyme-containing granules" (p.7-Arguments).

However, Kamal et al. specifically taught wherein the size of the core particles were "about 100 microns to about 2,500 microns" (col.4, lines 5-6). Although Applicant's are claiming ranges which state; i.e., no more than 1000 or 700 or 600 μ m, these ranges are obviated by Kamal et al.:



As can be seen in the diagram above, although Kamal et al. taught the range up to 2,500 micrometers, they nevertheless already disclosed the broad range overlapping the ranges disclosed by Applicants: In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed.Cir. 1990). One of ordinary skill in the art would have been motivated to have created enzyme containing particles in the claimed ranges because Kamal et al. clearly taught that the range as diagramed above were advantageous ranges for use in forming enzyme granules.

Because claims 39-41 claim ranges which overlap with the ranges disclosed by Kamal et al., these ranges are also obviated.

Wherein claims 42-45 recite certain percentages of the mass of the core unit in comparison to the mass of the granule, as stated in the previous Office action, Kamal et al. taught that the encapsulated core material particle comprised 10-80% by weight of a core material (claim 1). The term ‘about 5%’ has been given it’s broadest interpretation

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within reason and it is deemed that 10%, which was disclosed by Kamal et al. (claim 1 for example) is 'about 5%' lacking any clear definition within the Instant specification.

Claims 46-49 which recite at least 30, at least 50, at least 70 and at least 90% by weight of enzyme in the core unit are obviated by Kamal et al. because Kamal et al. taught a core particle of 100% enzyme (claim 2- 'wherein the core material is selected fromenzyme').

Wherein claims 54 and 55 recite 'wherein the granule comprises a multi-layered core unit' and 'wherein the granule comprises a clustered-particle core unit' are obviated since Kamal et al. taught that the core material was encapsulated by wax (i.e., claim 1). Thus, the wax was 'layered' onto the core particles. Kamal et al. clearly taught how to agglomerate the core particles (col.10, lines 25-68) thereby obviating claim 55.

Claims 7 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kame et al. (US 5,230,822) as applied to claims 1-6 and 9-10 above, and further in view of Paatz et al. (US 5,846,798).

Applicant's only argument pertaining to this rejection is that Kamal et al. did not obviate the claimed invention, and therefore Paatz et al. do not remedy Kamal et al. (p.8- Arguments). However, this argument is not found persuasive. As indicated supra,

Kamal et al. disclosed ranges which overlap with the claimed ranges thereby obviating said ranges. Therefore, this rejection stands.

Allowable Subject Matter

Claims 10, 51 and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

06/09/04

A handwritten signature in black ink, appearing to read "Patricia Leith", written in a cursive style.

**PATRICIA LEITH
PRIMARY EXAMINER**